

REMARKS

The Examiner rejected all pending claims under 35 USC 112, first paragraph because he claims that the specification, although enabling for itraconazole, budenoside, carbamazepine, prednisolone and nabumetone, does not reasonably provide enablement for other poorly water-soluble pharmaceutical compounds as claimed.

Applicants first bring the Examiner's attention to a Supplemental Amendment that was electronically filed April 6, 2007, before the mailing of the pending Office Action. This Supplemental Amendment was filed only to correct the inadvertent cancellation of claim 27 in a previous amendment (filed January 16, 2007). Applicants believe that the arguments made below apply to claim 27 as well as all other pending claims to which the Examiner refers in the pending Office Action (claims 1-18, 20, 22-26 and 28-46)

The Examiner applies the *In re Wands* factors to the present application. He first alleges that the claims are very broad. He also refers to the "lack of specific guidance from the instant specification" that would not allow *a priori* one of ordinary skill in the art to predict the particular combination method steps that would be suitable for the production of particles with particular desired characteristics for a particular compound. Consequently, he states that "painstaking" (i.e. presumably undue) experimentation would be required. The Examiner also asserts that there is high amount of unpredictability in the art. The Examiner admits that other *In re Wands* factors generally weigh in the favor of Applicants.

Applicants point out that for the enablement requirement to be satisfied, the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, the Court in *In re Wands* stated "The test (i.e. for undue experimentation) is not merely quantitative, since a considerable

amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed” *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976); emphasis added).

Applicants respectfully suggest that the disclosure of the present application meets this standard.

Applicants provide a Declaration under 37 CFR 1.132 from Dr. Mahesh Chaubal, the first-named inventor of the application. In the Declaration, Dr. Chaubal states that one of ordinary skill in the art would have sufficient guidance to practice the full scope of the claims without undue experimentation. In particular, applicants have disclosed detailed methods and assays that would provide guidance to one of ordinary skill in the art to make small particles of any poorly water soluble compound. Applicants have demonstrated the applicability of these methods and assays to five compounds (itraconazole, budenoside, carbamazepine, prednisolone and nabumetone) with widely different chemical structures, properties and uses. A person of ordinary skill in the art would conclude that the disclosure could be applied to a particular poorly water soluble compound and would not require an unusual amount of effort to determine if and how particles of the compound could be made.

Even assuming a high degree of unpredictability in the art, this is outweighed by the high degree of guidance provided by applicants. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicants also point out that the enablement requirement is still met even if inoperative embodiments fall within the scope of the claims. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414

(Fed. Cir. 1984) (prophetic examples do not make the disclosure non-enabling). Clearly applicants' description shows that the independent claims encompass several embodiments that are operative and are not required to show that any and all others would be operative.

Reconsideration and withdrawal of rejection is respectfully requested, as is the allowance of the present application.

Respectfully submitted,

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